CYNTHIA AXNE
3rd District, Iowa

Committee on Financial Services
Investor Protection, Entrepreneurship, and Capital Markets
Housing, Community Development and Insurance

Committee on Agriculture
Commodity Exchanges, Energy, and Credit
Conservation and Forestry

Congress of the United States
House of Representatives
Washington, DC 20515

Washington, DC Office
1034 Longworth House Office Building
Washington, DC 20515
(202) 225-5476

Des Moines Office
400 East Court Ave., Suite 346
Des Moines, IA 50309
(515) 400-8180

Council Bluffs Office
501 5th Ave.
Council Bluffs, IA 51503
(712) 890-3117

Creston Office
208 West Taylor
Creston, IA 50801
(515) 400-8180

May 17, 2022

The Honorable Robert M. Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Commissioner Califf:

On behalf of countless families across Iowa's Third Congressional District, I write to urge the Food and Drug Administration (FDA) to take all necessary steps to remedy the current infant formula shortage and prevent shortages from occurring again in the future.

For newborns and infants who cannot breastfeed, formula is the sole source of nutrition for which there is no alternative. This is particularly true for children with food allergies or gastrointestinal conditions that require specialty formula to meet their nutritional needs. However, the current formula shortage has forced parents into an impossible position. I've heard from Iowans spending hours hunting for formula only to find empty shelves and others debating whether to pay exorbitant prices from third-party sellers. Shortage conditions are also a breeding ground for fraudsters looking to capitalize on families' desperation.

A safe, steady supply of formula is indispensable to the health and development of babies in Iowa and across America. However, the available data suggests that infant formula, like other industries, is being impacted by supply chain issues. The nationwide out-of-stock percentage for baby formula rose above 10% nationwide at the end of 2021 and has continued to worsen over the course of this year. By April, the out-of-stock percentage hit 30% nationwide; it now stands at 43% nationwide and over 50% in Iowa.[1,2]

Undoubtedly, these supply issues have been exacerbated by the unsafe conditions requiring a temporary closure of Abbott's factory in Sturgis, Michigan after four cases of *Cronobacter sakazakii* infection were reported in infants who had consumed formula produced at the factory. Abbott ultimately bears responsibility for maintaining safe conditions at their factories, and Abbott knew of longstanding issues at this plant.[3] They neglected that responsibility~~,~~ and instead chose to return more than $5.7 billion to their shareholders in the form of stock buybacks, including $2.3 billion during the quarter this plant was closed. [4]

[1] https://datasembly.com/news/out-of-stock-rate-in-april-2022/
[2] https://datasembly.com/news/out-of-stock-rate-in-april-2022-copy/
[3] https://www.politico.com/news/2022/04/28/whistleblower-fda-baby-formula-00028569
[4] https://ycharts.com/companies/ABT/stock_buyback

While Abbott's decision to prioritize their stock buybacks over upkeep of their facility in order to keep American children safe is unconscionable, and the responsibility for reopening their Sturgis factory in a safe, sanitary manner lies with them, I believe the FDA must also seriously analyze its role in this situation. I am particularly concerned by the possibility that the FDA failed to act in a timely manner on a serious food safety issue and, moreover, failed to anticipate the likely effects on the nationwide supply of infant formula caused by a stoppage at the Sturgis factory.

Reports state that the first case of *Cronobacter sakazakii* infection linked to formula produced at Abbott's Sturgis facility was reported to the FDA in September 2021 by health officials in Minnesota. Around that same time, FDA inspection documents from that same period show the agency was aware Abbott's Sturgis facility was not being operated in a clean and sanitary manner.[5] Subsequent inspections of the Sturgis facility report that Abbott "did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated." Samples collected from the facility confirmed the presence of *Cronobacter sakazakii,* and inspectors also found at least 8 instances of contamination dating from fall 2019.[6]

Despite this fact pattern, the FDA did not warn consumers against using potentially contaminated formula produced by Abbott until February 17th, 2022. While I am grateful the FDA ultimately warned consumers, I believe the agency must account for the time period between when it first became aware of the *Cronobacter sakazakii* infections linked to the Sturgis facility and its first efforts to inform the public. Parents are rightfully asking how the infant formula shortage came to be, and they deserve accountability and transparency from the FDA.

I encourage the FDA to take a comprehensive and ongoing approach to shoring up our nation's supply of infant formula. In the immediate term, FDA must continue its efforts to reopen the Sturgis facility promptly and safely, pending court approval of its consent decree with Abbott. Over the longer term, the FDA must analyze and refine its procedures for inspecting formula manufacturers and instituting recalls, develop systems to anticipate and mitigate supply disruptions due to recalls, and work with relevant federal and state partners to increase the resiliency of the infant formula supply chain.

The current shortage must be quickly rectified, and we must take steps to prevent it from occurring again. I thank you for your attention to this critical matter, and I stand ready to work collaboratively to ensure a safe, robust, and reliable formula supply for infants in Iowa and across America.

Sincerely,

Cindy Axne

Member of Congress

[5] https://www.fda.gov/media/156747/download?utm_medium=email&utm_source=govdelivery
[6] https://www.fda.gov/media/157073/download?utm_medium=email&utm_source=govdelivery